4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0649]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: External Pacemaker Pulse Generator; Withdrawal of Draft Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of the draft guidance entitled "Class II Special Controls Guidance Document: External Pacemaker Pulse Generator," dated October 2011, in response to the requirements of the Food and Drug Administration Safety and Innovation Act (FDASIA) and new input received during a panel meeting.

DATES: The withdrawal is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Hina Pinto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1652, Silver Spring, MD 20993, 301-796-6351.

SUPPLEMENTARY INFORMATION:

In a notice published in the Federal Register of October 17, 2011 (76 FR 64228), FDA announced the availability of a draft special controls guidance document that, if finalized, would serve as a special control if FDA reclassified these devices. FDA believed that the special controls described in the draft guidance entitled, "Class II Special Controls Guidance Document:

External Pacemaker Pulse Generator" would be sufficient to mitigate the risks to health associated with the external pacemaker pulse generator (EPPG) (Ref. 1).

On July 9, 2012, FDASIA (Pub. L. 112-144) was enacted. Section 608(a) of FDASIA amended section 513(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(a)) changing the process for reclassifying a device from rulemaking to an administrative order. Subsequent to the publication of the proposed rule, FDASIA's amendments to section 513 of the FD&C Act required FDA to hold a classification panel (an FDA advisory committee) meeting to discuss the classification of this device type. On September 11, 2013, a meeting of the Circulatory System Devices Panel (the Panel) was held to discuss whether EPPG devices should be reclassified or remain as class III devices (Ref. 2). The Panel recommended that EPPG devices be reclassified to class II with special controls when intended for cardiac rate control or prophylactic arrhythmia prevention.

FDA provided an opportunity for interested parties to comment on the special control guidance on EPPG. FDA did not receive any comments to the docket. As a result of the Panel recommendation and the amendment to section 513(e) of the FD&C Act, FDA will now include the special controls for EPPG devices in a proposed order published elsewhere in this issue of the Federal Register and withdraw the draft guidance through this notice.

References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at http://www.regulations.gov. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Class II Special Controls Draft Guidance Document: External Pacemaker Pulse Generator, available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM275703.pdf.

2. The transcript and other meeting materials for the September 11, 2013, Circulatory System Devices Panel are available on FDA's Web site at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm342357.htm.

Dated: September 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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